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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,296	06/01/2006	**Sudhir Paul**		3694

7590 06/03/2010

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EXAMINER	
KOSAR, ANDREW D	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
06/03/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,296	PAUL ET AL.	
	Examiner	Art Unit	
	ANDREW D. KOSAR	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,10-22,25-28,30-34,44-48 and 62-65* is/are pending in the application.

4a) Of the above claim(s) *25-28,30-34,44-48,64 and 65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,10-22,62 and 63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments/Arguments

Applicant's amendments and arguments filed March 1, 2010 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below in original or modified form is herein withdrawn.

Claims 1-5, 10-22, 25-28, 30-34, 44-48 and 62-65 are pending. Applicant has amended claims 21, 22, 62 and 63. No claims have been cancelled in the amendment. Claims 25-28, 30-34, 44-48, 64 and 65 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 11, 2009.

With regards to the 112 1st ¶ rejection (new matter), Applicant argues the claims have been amended to overcome the rejection, asserting support is found in the specification, citing various portions of the specification. Respectfully, the examiner disagrees, to the extent of claims 62 and 63. The portions of the specification cited do not provide any indication that the language used in the claims is supported by the disclosure either by inherent, implicit or explicit description. While it is understood that the peptidic CAL of claims 21 and 22 inherently are made of amino acids, claim 63 describes the L variables as 'composed of an amino acid', however 'composed' is open language, allowing for any of a multitude of additional elements, so long as a single amino acid is present. The specification does not provide support for the L elements to be any sugar, lipid or nucleotide. The specification lacks a sufficient number of compounds of these genera to provide adequate support for any and all members therein, and

thus does not support the concept of the genera - sugar, nucleotide or lipid. Thus, for the reasons of record as amended below, the rejection is maintained for claims 62 and 63.

With regards to the 112 1st ¶ (written description) rejection, Applicant argues the CAL are described in the specification, citing the examples of the specification showing several CAL molecules contemplated. Applicant further argues that the moieties of the CAL are defined in the specification and that the specification provides ample guidance to "design and arrive at the compounds encompassed by claim 1 and dependent claims." Respectfully, the examiner disagrees. The specification is void of any definitions of the elements that form the CAL compounds in a manner that would provide the artisan with specific knowledge to carry out the invention. The definitions of the elements are vague and provide little insight into the structural aspects of the components, merely describing a function that is to be achieved, e.g. "a ligand structure unit that provides weak bonding interactions." This definition is identified by applicant as providing descriptive support for the compounds. Further, as indicated in the previous action, the examples of the specification and figures are greatly insufficient to describe the genus, particularly since there are no definitions in the specification that provide a structure/function relationship for the elements. One could not glean from these few compounds what is, or is not, embraced by the genus in any meaningful manner. Thus, for the reasons of record as restated below, the rejection is maintained.

With regards to the 112 2nd ¶ (missing essential elements) rejection, Applicant has not traversed this rejection directly, though the examiner has interpreted the response to the 112 1st rejections to embrace arguments addressing this rejection. Respectfully, the examiner finds the claims lack the essential elements of definitions for the various elements, including L_1 and L_m.

L_x is "a component unit of the ligand determinant" however L_1 and L_m have no definitions in the claim. Additionally, "ligand determinant" and "component unit of the ligand determinant" are undefined in the claims and specification in such a manner that the artisan is apprised of the meets and bounds of the claim. Thus, for the reasons of record restated below, the claims remain rejected.

With regards to the rejections under 102(b) (Tanaka), Applicant argues the compounds of the art are not anticipatory, in that the compound of Tanaka lacks a "covalently reactive electrophilic group". Upon further consideration, the examiner agrees that neither the primary amine or the serine hydroxyl are electrophiles.

With regards to the rejection under 102(e) (Paul) and to the obviousness double patenting (provisional and non-provisional), Applicant argues the claims have been amended and the compound shown are the reaction product of a hapten phosphonate monoester and trypsin followed by tryptic digestion. Applicant further states that "There is no precedent for a further exchange reaction of this end-product with a different NuR." Respectfully, the compound clearly meets the structural limitations set forth by the claim, and applicant traversal focuses on the use for further reaction with a different NuR. Applicant further argues the linker is different than what is disclosed in the reference structure, however the limitations argued are not found in the claims, and anything other than a direct bond necessarily qualifies as a linker, as a linker is generally any structure joining two segments, e.g. a two active therapeutics, a targeting moiety and a therapeutic, etc.. Structurally, the claims limitations are satisfied, and thus the compound must necessarily function as claimed. Accordingly, the rejections are maintained for the reasons of record, restated below.

Terminal Disclaimer

The terminal disclaimer filed on March 1, 2010 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of Application 10/581,294 has been reviewed and is NOT accepted.

Here, the filing date of 10/581,294 is incorrect on the submitted Terminal Disclaimer.

Accordingly, the provisional obviousness double patenting rejection has not been overcome.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 62 and 63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

MPEP § 2163 states that, "[n]ew or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389,1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads)." Further,

the MPEP states, "[w]hile there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure."

In the instant case, the scope of new claims 62 and 63 are not supported by implicit, inherent or explicit support. In both cases, the claims and specification provide no definition for L_1 and L_m, and thus one cannot conclude that they are composed of amino acids, lipids, sugars, polysaccharides, etc, as in claim 62 or 63.

Claims 1-5, 10-22, 62 and 63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Factors to be considered in making the determination as to whether one skilled in the art would recognize that the applicant was in possession of the claimed invention as a whole at the time of filing include: (a) Actual reduction to practice; (b) Disclosure of drawings or structural chemical formulas; (c) Sufficient relevant identifying characteristics such as: (i) Complete structure, (ii) Partial structure, (iii) Physical and/or chemical properties or (iv) Functional characteristics when coupled with a known or disclosed correlation between function and structure; (d) Method of making the claimed invention; (e) Level of skill and knowledge in the art and (f) Predictability in the art. While all of these factors are considered, a sufficient number for a *prima facie* case are discussed below.

Here, Applicant has provided few compounds, e.g. figure 18, which are within the scope of the claimed invention. Beyond these compounds, which are so closely related in structure,

Applicant has provided no description of compounds which are within the metes and bounds of the claims that would function as claimed- a covalently active ligand analog. The claims lack a description of L_1 and L_m, being defined as "components defining a ligand determinant" and L_x is "a component unit of the ligand determinant". Such description provides no complete or partial structure such that one would recognize the compounds envisaged by the claims. Furthermore, while synthesis of peptides are known to the artisan, synthesis of compounds with the requisite function is beyond the skill of the artisan, as one does not know the function required ("covalently active ligand analog") or what structure is required to impart such function, nor does the specification provide guidance as to how one would identify the required structure.

Although the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond those compounds specifically disclosed in the examples in the specification. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus. While having written description of the compounds identified in the specification tables and/or examples, the specification does not provide sufficient descriptive support for the myriad of compounds embraced by the claims.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and

does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 10-22, 62 and 63 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: definitions of L_1 and L_m. Applicant has defined the group of elements $L_1...L_x...L_m$ as "components defining a ligand determinant", and L_x as a component unit of the ligand determinant, where the ligand determinant is defined in a dependent claim as a polyamino acid, however L_1 and L_m are not defined in the claims.

Furthermore, it is unclear what is "a ligand determinant" as the claims and specification provides no definition. Additionally, it is unclear what is "a component of a ligand determinant".

Claim Rejections - 35 USC § 102

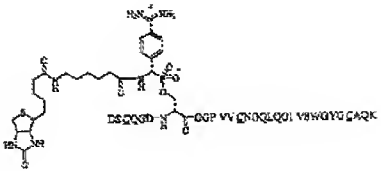
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 13, 18, 19, 21, 22, 62 and 63 are rejected under 35 U.S.C. 102(e) as being anticipated by PAUL (US 6,855,804 B2).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37

CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Paul teaches the compound:  (Figure 4B).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

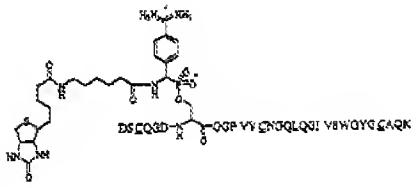
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 10-22, 62 and 63 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-66 of copending Application No. 10/581,294. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of '294 makes the compounds of the

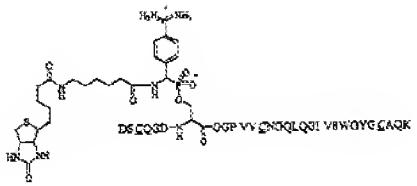
instant claims, and thus the final product of the synthesis of '294 is the claimed product of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-5, 10-22, 62 and 63 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 7,524,663 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds used in '663 anticipate the instant claims. In looking to the specification of '663 for the compounds used in support of the methods, one finds the compound:



Claims 1-5, 13, 18, 19, 21, 22, 62 and 63 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. US 6,885,804 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the covalently reactive transition state antigen analogs of '804 anticipate the instant CAL, sharing the same structure, with one species of '804 being:



Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims drawn to an invention nonelected with traverse in the reply filed on May 11, 2009. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW D. KOSAR whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew D Kosar/
Primary Examiner, Art Unit 1654